

We claim:

18 1. A method for evaluating the presence and severity of respiratory tract inflammation with or without infectious origin and the level of lung tissue injury, for predicting and for preventing the risk of complication, predicting the risk of an acute inflammation turning to a chronic process, for targeting the treatment modalities and medications to reduce tissue destruction with or without infectious origin and for evaluating the efficacy of an applied treatment, wherein the detection is performed as an immunochemical assay comprising the steps of:

a) obtaining a respiratory tract secretion sample representing whole or part of the lung;

b) contacting said sample with one or more binding substances capable of directly or indirectly recognizing one or more latent and/or active matrix metalloproteinases (MMPs) and/or related molecules (MMP-RMs) as well as activators, splice variants, inhibitors fragments, derivatives, complexes thereof either alone or in combination;

c) recording the presence of one or more of respiratory tract latent and/or active matrix metalloproteinases (MMPs) and/or related molecules (MMP-RMs) as well as fragments, splice variants, derivatives or complexes thereof either alone or in combination using one or more of the binding substances of step b) optionally tagged with a label capable of making the presence or absence of the MMPs and/or MMP-RMs alone or in combination recordable; and

d) assessing whether the MMPs and/or MMP-RMs recorded in step c) either alone or in combination are present in an amount which is essentially higher than in a sample from a healthy control person or animal.

- 19 2. The method according to claim 1, wherein the MMPs and/or MMP-RMs alone or in combination to be determined are selected from a group consisting of matrix metalloproteinases, membrane type matrix metalloproteinases and matrix metalloproteinase related molecules such as their activators, regulators, splice variants and/or inhibitors present in respiratory secretion samples.
- 20 3. The method according to claim 1, wherein the MMPs and/or MMP-RMs alone or in combination to be determined are selected from a group comprising latent and/or active MMP-2, MMP-8, MMP-9, MMP-13, MMP-14, MT1-MMP, NGAL, their isoforms as well as fragments, splice variants, derivatives and/or complexes thereof.
- 21 4. The method according to claim 1, wherein MMP-RMs are determined based as the total amount of one or more matrix metalloproteinases and/or related molecules in their latent form.
- 22 5. The method according to claim 1, wherein latent and/or active MMP-RMs are determined based the total amount of one or more MMPs and/or MMP-RMs alone or in combination in their active form.
- 23 6. The method according to claim 1, wherein the assessment is of step d is performed as a chair-side or bed-side test in a single step on an immunochromatographic test strip.
- 24 7. A test kit for evaluating the presence and severity of respiratory tract inflammation and the level of lung tissue injury, for predicting and preventing the risk of complication, for predicting the risk of an acute inflammation turning to a chronic process, for targeting the treatment modalities and medications to reduce tissue destruction with or without infection and for evaluating the efficacy of an applied treatment and medications using the method according to claims 1-5, wherein the test kit comprises one or more bind-

ing substances capable of specifically recognizing from a respiratory secretion sample representing whole or part of the lung one or more latent and/or active MMPs and/or MMP-RMs, their isoforms as well as fragments, splice variants, derivatives or complexes thereof either alone or in any combination as well as one or more optional substrates and or carriers.

25 8. The test kit according to claim 7, wherein the binding substances are antibodies capable of specifically recognizing latent and/or active MMPs and/or MMP-RMs alone or in combination selected from a group consisting of matrix metalloproteinases, membrane type matrix metalloproteinases and matrix metalloproteinase related molecules present in respiratory secretion samples.

26 9. The test kit according to claim 7, wherein the binding substances are antibodies capable of specifically recognizing matrix metalloproteinases and/or related molecules selected from a group consisting of MMP-2, MMP-8, MMP-9, MMP-13, MMP-14, (MT1-MMP) and NGAL as well as their activators, splice variants, regulators and/or inhibitors, their isoforms as well as fragments, derivatives and/or complexes thereof.

27 10. The test kit according to claim 7, wherein said binding substances are binding peptides, polyclonal antibodies, monoclonal antibodies and/or fragments of polyclonal or monoclonal antibodies.

28 11. The test kit according to claim 7, which in addition to a first binding substance being a monoclonal antibody which specifically recognizes at least one latent and/or active MMPs and/or MMP-RMs alone or in combination comprises at least one second binding substance, which recognizes another part of the same MMPs and/or MMP-RMs alone or in combination which different from the first mentioned MMPs and/or MMP-RMs.

29 12. The test kit according to claim 7, wherein at least one

of the binding substance capable of specifically recognizing MMPs and/or MMP-RMs alone or in combination is provided with a marker, which is adapted to give a positive signal only when the concentration of MMPs and/or MMP-RMs alone or in combination is above the concentration in samples from healthy controls.

30 13. The test kit according to claim 7, wherein the test kit is constructed as an immunochromatographic test strip on which the recordation and assessment can be performed in a single step as a chair-side or bed-side test.

31 14. The use of binding substances recognizing one or more MMPs and/or MMP-RMs alone or in combination for diagnosing, monitoring and/or screening the level, severity and/or disease activity phase respiratory tract inflammation, for targeting the drug treatments, medications, treatment modalities, for predicting the risks caused by pro-inflammatory mediators, infectious agents as well as physical and/or environmental stress factors.

32 15. The use of binding substances recognizing one or more MMPs and/or MMP-RMs alone or in combination for manufacturing test kits for diagnosing the level, severity and/or disease activity phase(s) of respiratory tract inflammation, for targeting the treatment modalities, for predicting the risks caused by pro-inflammatory mediators, infectious agents as well as physical and/or environmental stress factors.

33 16. The use of one or more MMPs and/or MMP-RMs alone or in combination as markers for diagnosing the level, severity and/or disease activity phase(s) of respiratory tract inflammation, for targeting the treatment modalities and medications, for predicting the risks caused by physical stress and/or environmental factors to risk group individuals.

34 17. The uses according to claims 14-16, wherein the MMPs

and/or MMP-RMs alone or in combination are used to prepare binding substances specifically recognizing said molecules and for preparing a chair-side or bed-side test kit enabling the evaluation of the severity of respiratory inflammation in a single step on an immunochromatographic test strip.

*Add a2*